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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/801,968	03/07/2001	Nobuyuki Itoh	PP-17150.001 / 201130.409	8729

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EXAMINER
SAOUD, CHRISTINE J

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 12/04/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/801,968

Applicant(s)

ITOH et al.

Examiner

Christine Saoud

Art Unit

1647



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 13, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above, claim(s) 1-11, 19-21, and 23-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-18 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 8-11 6) ☐ Other:

DETAILED ACTION

Election/Restriction

1. ~~Applicant's election with traverse of Group II, claims 12-18, 22 and 53-57 and the~~
polypeptide having the sequence of (a) (in claim 12) in Paper No. 14 is acknowledged. The traversal is on the ground(s) that "a search of all of (a)-(h) would not be an undue burden" because the polypeptide recited in these claims are whole or partial contiguous amino acid sequence of SEQ ID NO:4. This is not found persuasive because a search of items (a)-(h) is not coextensive. For example, a search of (c) is independent of (d), (g) and (h) and a search of (e) is independent of (g) and (h). Additionally, art which is obtained for the full length molecule of SEQ ID NO:4, amino acids 1-251, is not necessarily art for the independent and distinct fragments listed in items (b)-(h). Therefore, each fragment would need to be searched and separate art would need to be considered for each listed embodiment.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-11, 19-21, 23-52, 58-60 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 14.

Additionally, claims 53-57 are also withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention (related to SEQ ID NO:2, and not the elected SEQ ID NO:4, amino acids 1-251), there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 14. Claims 12-18 and 22 are under examination in the instant application.

Drawings

3. Figures 2, 3, 7-9, 13 and 15 of the instant application is presented on separate pages and/or panels. Although the Figures are correctly labeled according to 37 C.F.R. § 1.84 (U)(1), which requires that when partial views of a drawing which are intended to form one complete view must be identified by the same number followed by a capital letter, the Brief Description of the Drawings beginning at page 4 does not properly refer to the Figures, in that the partial views are not indicated. The Brief Description of the Drawings must also refer to the Figures in terms of the partial views (in that each view is considered a separate Figure); for example, Figure 2 is divided into Figures 2A and 2B, therefore the Brief Description and all references to this Figure in the specification must refer to Figures 2A and/or 2B. Correction is required.

Sequence Compliance

4. Page 40, Table 1 of the specification contains amino acid sequences without a corresponding sequence identifier. All amino acid sequences which are longer than 4 amino acids require the use of a sequence identifier (MPEP 2422 and 37 CFR 1.821 (d)). Correction is required.

Specification

5. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. For example, the invention is not directed to a gene, but to a polypeptide and compositions thereof.

6. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

7. The abstract of the disclosure is objected to because it contains speculative applications of the invention (i.e. reference to diagnostic and therapeutic applications). Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 101

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 15-18 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims fail to include any limitations which would distinguish the claimed proteins, peptides and compositions from those which occur in nature. In the absence of the hand of man, naturally occurring nucleic acid molecules and proteins are considered non-statutory subject matter. Diamond v. Chakrabarty, 206 USPQ 193 (1980). Additionally, mere purity of a naturally occurring product does not necessarily impart patentability. Ex parte Siddiqui, 156 USPQ 426

(1966). However, when purity results in a new utility, patentability is considered. Merck Co. v. Chase Chemical Co., 273 F. Supp. 68 (1967). Filing of evidence of a new utility imparted by the ~~increased purity of the claimed invention and amendment of the claims to recite a purity limitation,~~ if supported by the specification, is suggested to obviate this rejection. Applicant should point to the basis in the specification for any amendment to the claims. The claims are directed to an epitope-bearing portion of a polypeptide, however, the entire protein can be considered an epitope-bearing portion. Furthermore, since the dependent claims include open language of “comprising”, this fails to limit the polypeptides to any particular fragment or portion, thereby encompassing the protein as it occurs in nature.

10. Claims 12-18 and 22 are rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility. The instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose the biological role of the nucleic acid, the encoded protein or the significance of either.

It is clear from the instant specification that the “FGF-23” (SEQ ID NO:4) described therein is what is termed an “orphan protein” in the art. This is a protein whose cDNA has been isolated because of its similarity to known proteins. There is little doubt that, after complete characterization, this protein, and the nucleic acid encoding it, may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant’s claimed invention is incomplete. The

instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to ~~other compounds which were known to possess anti-cancer activity was alleged to be potentially~~ useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are “useful” to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of “useful” as it appears in 35 U.S.C. §101, which requires that an invention must have either an immediately obvious or fully disclosed “real world” utility. The court held that:

“The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility”, “[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field”, and “a patent is not a hunting license”, “[i]t is not a reward for the search, but compensation for its successful conclusion.”

The instant claims are drawn to a protein of as yet undetermined function or biological significance. The specification asserts at pages 3-4 of the specification that the claimed compositions could be used for “preventing or slowing the degeneration of or increasing the numbers of skin cells, in disease states including but not limited to, abnormal proliferation, atrophy, degeneration, toxin-mediated tissue damage, and post-surgical and post-injury tissue regeneration; of preventing or slowing degeneration of or increasing the numbers of cells of the thymus in disorders of the thymus and immune systems; and of preventing or slowing the degeneration of neuronal tissue, or increasing the number of neural cells, such as in Parkinson’s

Disease and Alzheimer's Disease" as well as use of inhibitors for treatment of cancers and proliferative or differentiation disorders of cells derived from the thymus, neural tissue, skin or placenta. However, there is no evidence of record that the claimed polypeptide and/or compositions would have any activity that would result in the treatment of any disease or condition asserted in the instant specification.

The specification points out at pages 5-6 that FGF's have a number of different activities in a variety of cells and tissue types. It should be noted that members of the FGF family of proteins fail to share a common utility based on a common structural feature due to the variety of cells and tissue types which are affected and it is not clear or predictive which activity of the FGF family will be possessed by the disclosed protein based on structural similarity alone. The protein of the instant specification is a compound which is known to share some structural similarity to the FGF family of proteins which are known in the art to have biological significance in regulation of cell proliferation, differentiation, and function based on sequence similarity to members of the FGF-family. However, as indicated in Galzie et al. (Biochem. Cell Biol. 75: 669-685, 1997), the FGF family is complex and diverse (see abstract). Table 1 of Galzie et al. details the biological significance of the first 9 members of this protein family, wherein none of the associated functions are found in common with any other family member. In the absence of a knowledge of the biological significance of the disclosed "FGF-23", there is no immediately obvious patentable use for it. The instant specification fails to teach or describe which biological activity is possessed by the encoded polypeptide of the claimed nucleic acid and one of ordinary skill in the art cannot discern the biological activity based on the amino acid sequence structure alone. The specification

states that the gene for the claimed polypeptide is localized on chromosome 19p13.3 and that the protein is expressed in the thymus, skin, brain and placenta and therefore, "may play a role in development of and recovery from disease of these tissues". However, without a knowledge of the biological significance of the claimed polypeptide, what role is to be played, if any, has not been determined and any use of the claimed invention would be purely as an object of further research and characterization. Expression of a protein in a given tissue is not conclusive or necessarily suggestive of the function of that protein in a given tissue. A protein could be stimulatory or inhibitory, or it could be produced in one tissue and have biological effects on another tissue. One cannot conclude function from tissue expression patterns alone, especially for a protein from a family which has such diversity in function as the FGF family. Furthermore, the prior art of record demonstrates that the biological function of the protein family to which the disclosed protein is said to be a member is so diverse, that one could not predict which biological activity is possessed by the disclosed protein based on structural similarity alone, especially since all the members share structural similarity, but not functional similarity. The specification states that the claimed polypeptide may play a role in precancerous lesions, repair following inflammatory disease, trauma, or toxin-related injury, and other diseases of the skin, disorders of cells such as immune cells derived from the thymus, for example, autoimmune disorders, leukemias and lymphomas, immune deficiency states and the like (see pages 15-16 of the specification). The specification further asserts a use of the claimed polypeptide for preventing cell death and restoring function of dopamine producing neurons (see pages 16-17) as well as for treatment of neurodegenerative diseases such as Alzheimer's, Parkinson's, stroke, brain trauma,

toxic insults of the central nervous system, and other CNS or neurological disorders, as well as other diseases including Crohn's disease, healing of intestinal wounds, ulcers, inflammation, injuries and surgical anastomoses, motility and absorption disorders and congenital malformations of the intestine and uses related to placental function, such as fertility, congenital defects, and disorders of the placenta (see page 19 of the specification). There is no evidence of record that the claimed polypeptide has any activity which would result in the treatment of any of the asserted conditions/diseases/disorders in the instant specification. Not all members of the FGF family have mitogenic activity on all of the cell types listed, and many if not most are specific to particular cell types. This means that one must know *a priori* which cells the FGF protein acts on in order to use the claimed polypeptide in a real world manner. For example, KGF does not stimulate fibroblast cells, but is specific for keratinocyte cells. Without the knowledge of this specificity, one would not be able to use KGF (also known as FGF-7) in a real world manner, and one could clearly not use it as a mitogen for all of the cell types identified in the instant application.

The specification asserts a number of conditions, disorders and/or disease which "may" be treated by administration of the claimed polypeptide. However, without a disclosure of the biological role or significance of the claimed polypeptide, one of ordinary skill in the art would not be able to use the claimed invention for the treatment of any of the listed conditions, disorders or diseases because it is not taught which activity is possessed by the encoded polypeptide, and therefore, which condition, disorder, or disease could be treated by the disclosed polypeptide. Neither the specification nor the prior art demonstrates a causal correlation or nexus of the claimed invention with any of the conditions or disorders contemplated by the instant

specification, therefore, there is no evidence of record that would provide for a method of treating/diagnosing any of the listed conditions or disorders. There is absolutely no evidence of record or any line of reasoning that would support a conclusion that the "FGF-23" of the instant application is involved in regulating growth and/or differentiation of any *particular* cell population. The record fails to indicate any evidence of any of these biological activities, and it would appear that until some actual and specific significance can be attributed to the protein identified in the specification and the gene encoding it, the instant invention is incomplete.

To employ the instant invention in any of the disclosed methods would clearly be using it as the object of further research which has been determined by the courts to be a utility which, alone, does not support patentability. Since the instant specification does not disclose a credible "real world" use for the claimed invention, it is incomplete and, therefore, does not meet the requirements of 35 U.S.C. §101 as being useful.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 12-18 and 22 are rejected under 35 U.S.C. §112, first paragraph, as failing to adequately teach how to use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. §101.

13. Claims 12-13 and 22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims encompass polypeptides having at least 95% sequence identity to SEQ ID NO:4 or having "at least one conservative amino acid substitution", the second of which encompass unlimited substitutions. The instant specification fails to describe polypeptides which meet these limitations of these claims. First, the instant specification teaches two examples of a polypeptide (SEQ ID NO:2 and 4), but fails to teach any polypeptides having the recited % identity to SEQ ID NO:4 (SEQ ID NO:2 is only about 70% identical to SEQ ID NO:4). In making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, it is necessary to understand what Applicant has possession of and what Applicant is claiming. From the specification, it is clear that Applicant has possession of a protein which has the amino acid sequence of SEQ ID NO:4. The subject matter which is claimed is described above. First, a determination of the level of predictability in the art must be made in that whether the level of skill in the art leads to a predictability of structure; and/or whether teachings in the application or prior art lead to a predictability of structure. The claims are directed to polypeptide which have sequence identity to the disclosed polypeptide of SEQ ID NO:4, or an unlimited number of substitutions in the sequence. First, the claims are not limited to any particular polypeptide, in that the claims are directed to variant forms. The specification only describes two polypeptides and fails to teach or describe any other molecules

claims. The breadth of the claims is such that the claims encompass polypeptides from other species, related polypeptides and variants which have yet to be described, as well as proteins which are not required to share any sequence identity to the disclosed sequence of SEQ ID NO:4.

There is a lack of guidance or teaching regarding structure and function of the polypeptide because there are only two examples provided in the specification and because there is no guidance found in the prior art for this specific polypeptide, including a lack of disclosure of activity for the polypeptide.

Next in making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, each claimed species and genus must be evaluated to determine whether there is sufficient written description to inform a skilled artisan that applicant was in possession of the claimed invention at the time the application was filed. With this regard, the instant application fails to provide a written description of the species or the genus which are encompassed by the instant claims except for the polypeptide of SEQ ID NO:4, and possibly that of SEQ ID NO:2. The specification does not provide a complete structure of those molecules which have the recited % sequence identity to SEQ ID NO:4 or that have unlimited amino acid substitutions. The claims also fail to recite other relevant identifying characteristics (physical and/or chemical and/or functional characteristics coupled with a known or disclosed correlation between function and structure) sufficient to describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention. The specification fails to provide a representative number of species for the claimed genus because the specification only teaches two

embodiments. Therefore, the claims are directed subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim Rejections - 35 USC § 112

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claims 12-14 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 12-14 are indefinite for the recitation of "amino acids from about 1 to about 251" because the metes and bounds of "about" cannot be determined from the claims. Even though the use of the term "about" in a claim is inherently vague and indefinite, its use is appropriate when employed to limit a value which is composed of infinitely divisible units such as inches, meters, grams and pints where it is impractical to produce an item which has exactly the dimension recited. Even if one could practically produce an item which is exactly 1 inch in length, the length of that item is conditional upon the temperature at which it is measured. However, when defining an invention in terms of indivisible numerical units such as the number of nucleotides in a nucleic acid, the number of amino acids in a polypeptide or the number of legs on a chair or table, the term "about" is unacceptably vague and indefinite since it is practical to employ a term which possesses the required precision. If, for example, it is Applicant's intention that the claims should

encompass a polypeptide of no more than 32 amino acids in length then this is exactly what the claim should recite. Whereas one would reasonably interpret the term "about one inch" as encompassing any value from 0.90 inches to 1.10 inches one would not know if the term "from about 1 to about 251" would include or exclude amino acid 2, amino acid 3, or even amino acid 10. Claim 22 is also rejected as it depends from claim 12.

Claim 12 recites a "polypeptide comprising amino acids at least 95% identical to amino acids selected from the group consisting of". However, there is no indication that the sequence of the amino acids must be retained, therefore, it would appear that the instant claims encompass any protein wherein the amino acids are 95% identical. Because the amino acids in naturally occurring proteins are going to be identical, in that each protein will have the same type of serine or alanine or cysteine, etc, it would appear that the instant claims encompass all isolated proteins. Since this appears to be unreasonable, the metes and bounds of what is claimed is indefinite. The addition of the term "sequence" to the claim would clarify this issue. Although art would be applicable in view of this interpretation, it will not be applied at this time since it is most likely a typographical error in the drafting of the claim.

Claim 13 is indefinite for the recitation of "conservative amino acid substitution". Conservation can be in terms of conservation of protein structure, protein function or in terms of amino acid structure. Without knowing what is being conserved, the claims are indefinite for what would constitute a conservative substitution.

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

17. Claim 13 is rejected under 35 U.S.C. 102(b) as being anticipated by Smallwood et al. (Proc. Natl. Acad. Sci. USA. Vol. 93, 9850-9857, 1996).

Smallwood et al. describe a number of FGF-related molecules (see abstract and Figure 1). These molecules have at least one conservative amino acid substitution, as required in the claim, and therefore, these molecules meet the structural limitations of the claim. Because the term “conservative” is not defined, it would appear that conservation of some function of the FGF family is encompassed, and since these molecules are members of the FGF family, they share a function that may be conserved. The claim is anticipated by the molecules of Smallwood et al., especially in light of the limitation of “at least one” substitution, which sets no upper limit on how much of the molecule may be substituted.

18. Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Mahmood et al. (Development 121: 1399-1410, 1995).

Mahmood et al. teach a polypeptide which comprises 6 contiguous amino acids in common with SEQ ID NO:4 (see Figure 1 and attached alignment). This would appear to be an epitope containing portion of SEQ ID NO:4 as required by the claim. Therefore, the claim is anticipated by the prior art.

Conclusion

19. No claim is allowed.

~~Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Christine J. Saoud, Ph.D., whose telephone number is (703) 305-7519. The Examiner can normally be reached on Monday to Thursday from 8AM to 2PM. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.~~

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. §§ 1.6(d) and 1.8). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternate number. Official papers filed After Final rejection filed by fax should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

**CHRISTINE J. SAOUD
PRIMARY EXAMINER**

Christine J. Saoud